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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/529,064	08/02/2005	Pierre Michel Desmons		4877

20462 7590 11/28/2006

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EXAMINER	
GANGLE, BRIAN J	
ART UNIT	**PAPER NUMBER**
1645	

DATE MAILED: 11/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/529,064	DESMONS ET AL.	
	Examiner	Art Unit	
	Brian J. Gangle	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *18 September 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14* is/are pending in the application.

4a) Of the above claim(s) *11-14* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's amendment and response filed 9/18/2006 is acknowledged. Claims 1-14 are pending. Claims 11-14 are withdrawn as being drawn to non-elected inventions. Claims 1-10 are currently under examination.

Objections Withdrawn

The objection to the specification because the title of the invention was not descriptive is withdrawn in light of applicant's amendment thereto.

Claim Rejections Withdrawn

The rejection of claim 6 under 35 U.S.C. 112, second paragraph, as being indefinite because it contained a broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim), is withdrawn in light of applicant's amendment thereto.

The rejection of claim 7 under 35 U.S.C. 112, second paragraph, as being rendered vague and indefinite by the phrase "capsular polysaccharides selected from the following list of serotypes: A, C, Y and W," is withdrawn in light of applicant's amendment thereto.

Claim Rejections Maintained

35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The rejection of claim 2 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is maintained for the reasons set forth in the previous office action.

Applicant argues: that the phrase "meningococcal strain with a serosubtype that is prevalent in a country of use" is defined in the specification and is not unclear. The specification states: "By a "meningococcus strain with a serosubtype that is prevalent in a country of use" it is

meant the bleb is derived from a meningococcal strain with a serosubtype which is most prevalent (or possibly second or third or fourth prevalent--particularly if 2 or 3 or 4 bleb preparations with homologous bactericidal activity are incorporated in the vaccine) in percentage terms amongst strains of all serosubtypes which cause meningococcal disease in the country (or region or continent)--i.e. strains isolated during laboratory-based active surveillance of meningococcal disease in a country, region or continent Preferably the serosubtype of such a bleb constitutes more than 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 15, 20, 30, 40, 50 or 60% of all serosubtypes which cause meningococcal disease in the country (or region or continent)."

Applicant's arguments have been fully considered and deemed non-persuasive.

The specification does not provide a clear, specific, limiting definition. The use of the language "most prevalent (or possibly second or third or fourth prevalent..." renders the definition unclear. Does applicant intend the definition of prevalent to mean first, second, third or fourth prevalent? Does applicant intend that "prevalent" might be first, second, third or fourth prevalent, but could be something else?

35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The rejection of claims 1-9 under 35 U.S.C. 102(b) as being anticipated by Berthet *et al.* (PCT Publication WO 01/09350, 2/8/2001) is maintained for the reasons set forth in the previous office action.

Applicant argues: that the examiner has incorrectly suggested that Berthet *et al.* teaches a mixture of a Neisserial strain with 20% PorA (CU-385) and a strain with 30% PorA (H44/76). The examiner showed that CU-385 has a serotype of P1.15, and that H44/76 has a serotype of P1.7,16; and that, since Berthet *et al.* teaches a mixture of these serotypes, Berthet *et al.* therefore teaches a mixture of a Neisserial strain with 20% PorA and a strain with 30% PorA. Applicant

argues that CU-385 is deficient in PorA, but not all strains of the serotype P1.15 are deficient in PorA; therefore, Berthet *et al.* does not teach a mixture containing a strain deficient in PorA, but a mixture containing any member of the serotype P1.15.

Applicant's arguments have been fully considered and deemed non-persuasive.

Applicant is correct that CU-385 is deficient in PorA and that not all strains of the serotype P1.15 are deficient in PorA. However, Berthet *et al.* specifically discloses a mixture of strains H44/76 and CU-385 (see page 35, lines 20-26). Because CU-385 is deficient in PorA, and H44/76 is not deficient in PorA, the mixture disclosed by Berthet *et al.* meets all of the limitations of the instant claims.

As stated previously, the instant claims are drawn to a multivalent meningococcal bleb composition comprising a bleb preparation deficient in PorA in that it has less than 80% of the amount of PorA as compared to the same quantity of blebs made from strain H44/76 and a bleb preparation that is not deficient in PorA compared to blebs made from strain H44/76 (claim 1). Further limitations found in dependent claims include the composition of claim 1 wherein the bleb preparation that is not deficient in PorA is derived from a meningococcal strain with a serosubtype that is prevalent in a country of use (claim 2); wherein the bleb preparation deficient in PorA has less than 22% PorA of total bleb protein, or lacks PorA (claim 3); wherein the bleb preparation not deficient in PorA has more than 28% PorA of total bleb protein (claim 4); and wherein the bleb preparation deficient in PorA is derived from the meningococcal CU-385 strain (claim 5). The instant claims further include a vaccine for the treatment of neisserial disease comprising the multivalent meningococcal bleb composition of claim 1 and a pharmaceutically acceptable excipient (claim 6). Further limitations found in dependent claims include the vaccine of claim 6 additionally comprising one or more plain or conjugated meningococcal capsular polysaccharides selected from the following list of serogroups: A, C, Y and W (claim 7); wherein the bleb preparation that is not deficient in PorA is derived from a meningococcal strain with a serosubtype of P1.4 (claim 8); and wherein the bleb preparation that is not deficient in PorA is derived from a meningococcal strain with a serosubtype of P1 .7,16 (claim 9).

Berthet *et al.* disclose a multivalent vaccine comprising mixtures of meningococcus bleb preparations as well as a pharmaceutically acceptable excipient (see page 36, lines 5-28 and page 33, lines 1-5). Said vaccine comprises mixtures of bleb preparations from 2 or more strains,

including serotypes P1.15, P1.7,16, and P1.4 (see page 36, lines 15-19). Said vaccine is also disclosed as comprising any or all of the capsular polysaccharides A, C, Y, or W (see page 36, lines 11-14). It should be noted that applicant discloses, in the instant specification, that P1.15 is the serosubtype of strain CU-385, which has 20% PorA (see page 22, lines 19-22 and page 24, lines 8-11) and that P1.7,16 is the serosubtype of strain H44/76, which has 30% PorA (see page 6, line 18 and page 25, table 1). Therefore, the disclosure of Berthet *et al.* anticipates the instantly claimed invention.

The rejection of claims 1-9 under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Granoff *et al.* (PCT Publication WO 02/09643, 2/7/2002), is maintained for the reasons set forth in the previous office action.

Applicant argues:

1. That the compositions in Granoff *et al.* differ from the presently claimed comopositions because there is no disclosure of a composition comprising blebs deficient in PorA with blebs which are not, and that Granoff *et al.* show no concern for the level of PorA whatsoever.

2. That Granoff *et al.* concentrate on how sequential administration of different blebs induces a better immune response than when those blebs are mixed in a single composition. Applicant states that sequential administration induced high levels of bactericidal anti-CU-385 antibodies, but administration of a mixture led to no bactericidal antibodies.

3. That Granoff *et al.* not only does not motivate one to use a composition comprising two or more blebs, but also teaches away from a composition comprising a mixture of blebs. Applicant's argue that Granoff *et al.* shows the use of sequential administration (rather than mixtures) is the preferred embodiment and that sequential administration was better than a mixture in terms of bactericidal activity against strains CU-385 and 1000.

Applicant's arguments have been fully considered and deemed non-persuasive.

Regarding argument 1, Granoff *et al.* does not show concern for the level of PorA in the disclosed compositions. However, Granoff *et al.* disclose vaccines that contain blebs from multiple strains of *Neisseria.* Granoff *et al.* disclose the "Norwegian Vaccine" which contains blebs from strain H44/76 (see page 5, lines 5-10), and Granoff *et al.* disclose mixtures which

contain blebs from strain CU-385 (see page 48, lines 22-23). While Granoff *et al.* do not address the level of PorA, the disclosed strains are those which have the levels claimed by applicant, and indeed, are the same strains used by applicant in the instant invention.

Regarding arguments 2 and 3, in their arguments, applicant admits that Granoff *et al.* disclose a vaccine comprising a mixture of blebs. While sequential administration may be the preferred embodiment, and may have produced higher levels of bactericidal antibodies, Granoff still discloses that a vaccine containing a mixture does induce bactericidal antibodies and does disclose a vaccine comprising a mixture of blebs. Granoff *et al.* specifically states "the vaccine and immunization regimen of the invention provides its unexpected advantages in broad spectrum protective immunity." Granoff *et al.* also specifically states that the outer membrane vesicles can be administered serially **or as a mixture** (page 22, lines 29-30). This is an explicit motivation for combining blebs into a vaccine. Serial administration may have been more effective, but the mixture did induce bactericidal antibodies. Further, both a composition containing CU-385 and one containing H44/76 are disclosed as effective vaccines. According to MPEP 2144.06, "It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980).

As stated previously, the instant claims are drawn to a multivalent meningococcal bleb composition comprising a bleb preparation deficient in PorA in that it has less than 80% of the amount of PorA as compared to the same quantity of blebs made from strain H44/76 and a bleb preparation that is not deficient in PorA compared to blebs made from strain H44/76 (claim 1). Further limitations found in dependent claims include the composition of claim 1 wherein the bleb preparation that is not deficient in PorA is derived from a meningococcal strain with a serosubtype that is prevalent in a country of use (claim 2); wherein the bleb preparation deficient in PorA has less than 22% PorA of total bleb protein, or lacks PorA (claim 3); wherein the bleb preparation not deficient in PorA has more than 28% PorA of total bleb protein (claim 4); and wherein the bleb preparation deficient in PorA is derived from the meningococcal CU-385 strain (claim 5). The instant claims further include a vaccine for the treatment of neisserial, preferably

meningococcal, disease comprising the multivalent meningococcal bleb composition of claim 1 and a pharmaceutically acceptable excipient (claim 6). Further limitations found in dependent claims include the vaccine of claim 6 additionally comprising one or more plain or conjugated meningococcal capsular polysaccharides selected from the following list of serotypes: A, C, Y and W (claim 7); wherein the bleb preparation that is not deficient in PorA is derived from a meningococcal strain with a serosubtype of P1.4 (claim 8); and wherein the bleb preparation that is not deficient in PorA is derived from a meningococcal strain with a serosubtype of P1 .7,16 (claim 9).

Granoff *et al.* disclose an outer membrane vesicles (bleb) vaccine that comprises a mixture of blebs from genetically diverse strains of *Neisseria meningitidis* as well as a pharmaceutically acceptable excipient (see page 6, lines 23-31 and page 22, lines 5-20). Granoff *et al.* also disclose a bleb vaccine that contains a mixture of blebs from a serogroup C strain as well as a strain with the serogroup P1.4 (see page 7, lines 19-27). Granoff *et al.* further disclose individual bleb vaccines that each comprise strains with the serosubtypes P1.15 (CU-385) and P1.7,16 (see figure 1). Additionally, Granoff *et al.* disclose that the disclosed mixture vaccine has the advantage of broad spectrum protective immunity (see page 15, lines 10-12). It should be noted that applicant discloses, in the instant specification, that P1.15 is the serosubtype of strain CU-385, which has 20% PorA (see page 22, lines 19-22 and page 24, lines 8-11) and that P1.7,16 is the serosubtype of strain H44/76, which has 30% PorA (see page 6, line 18 and page 25, table 1).

Granoff *et al.* do not explicitly disclose that the bleb vaccine mixture should contain strains with serosubtypes P1.15 (CU-385) and P1.7,16.

However, it would have been *prima facie* obvious to a person of ordinary skill in the art at the time of invention to use the strains with serosubtypes P1.15 (CU-385) and P1.7,16 in the mixture of the bleb vaccine in order to obtain the advantage of broad spectrum protective immunity, as disclosed by Granoff *et al.* Therefore, the use of the serosubtypes P1.15 (CU-385) and P1.7,16 in the mixture of the bleb vaccine is deemed an obvious variation of the disclosed composition.

35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The rejection of claims 1-10 under 35 U.S.C. 103(a) as being unpatentable over Berthet *et al.* (PCT Publication WO 01/09350, 2/8/2001) in view of Lehmann *et al.* (APMIS 99:769-772, 1991), is maintained for the reasons set forth in the previous office action.

Applicant argues:

1. That the examiner has provided no motivation that would impel persons of ordinary skill to combine the teachings of the cited references and that the examiner has not shown that there was a reasonable expectation of success in combining the compositions of the cited references.

2. That, for the same reasons stated above, Berthet *et al.* does not disclose a mixture of blebs where one is deficient in PorA.

3. That, because there is no discussion of the utility of PorA deficient blebs in multivalent bleb compositions, there can be no motivation to combine, and if the references were combined, the instant invention could not be arrived at without hindsight.

Applicant's arguments have been fully considered and deemed non-persuasive.

Regarding argument 1, in response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, as stated in MPEP 2144.06, and in the previous office action, "It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980). One would have had a reasonable expectation of success based on the success already shown with each of the components of the composition.

Regarding argument 2, as discussed above, Berthet *et al.* disclose a mixture containing blebs from strain CU-385 (which is deficient in PorA, according to applicant).

Regarding argument 3, Berthet *et al.* discuss the utility of a vaccine containing a mixture of blebs from strains deficient in PorA (CU-385) and strains not deficient in PorA (H44/76), and as stated above, it is obvious to combine to compositions taught by the art to be useful for the same purpose. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

As stated previously, the instant claims are drawn to a multivalent meningococcal bleb composition comprising a bleb preparation deficient in PorA in that it has less than 80% of the amount of PorA as compared to the same quantity of blebs made from strain H44/76 and a bleb preparation that is not deficient in PorA compared to blebs made from strain H44/76 (claim 1). Further limitations found in dependent claims include the composition of claim 1 wherein the

bleb preparation that is not deficient in PorA is derived from a meningococcal strain with a serosubtype that is prevalent in a country of use (claim 2); wherein the bleb preparation deficient in PorA has less than 22% PorA of total bleb protein, or lacks PorA (claim 3); wherein the bleb preparation not deficient in PorA has more than 28% PorA of total bleb protein (claim 4); and wherein the bleb preparation deficient in PorA is derived from the meningococcal CU-385 strain (claim 5). The instant claims further include a vaccine for the treatment of neisserial, preferably meningococcal, disease comprising the multivalent meningococcal bleb composition of claim 1 and a pharmaceutically acceptable excipient (claim 6). Further limitations found in dependent claims include the vaccine of claim 6 additionally comprising one or more plain or conjugated meningococcal capsular polysaccharides selected from the following list of serotypes: A, C, Y and W (claim 7); wherein the bleb preparation that is not deficient in PorA is derived from a meningococcal strain with a serosubtype of P1.4 (claim 8); wherein the bleb preparation that is not deficient in PorA is derived from a meningococcal strain with a serosubtype of P1 .7,16 (claim 9); and wherein the bleb preparation that is not deficient in PorA is derived from a meningococcal strain with a serosubtype of P1.16 (claim 10).

Berthet *et al.* disclose a multivalent vaccine comprising mixtures of meningococcus bleb preparations as well as a pharmaceutically acceptable excipient (see page 36, lines 5-28 and page 33, lines 1-5). Said vaccine comprises mixtures of bleb preparations from 2 or more strains, including serotypes P1.15, P1.7,16, and P1.4 (see page 36, lines 15-19). Said vaccine is also disclosed as comprising any or all of the capsular polysaccharides A, C, Y, or W (see page 36, lines 11-14). Applicant discloses in the instant specification that P1.15 is the serosubtype of strain CU-385, which has 20% PorA (see page 22, lines 19-22 and page 24, lines 8-11). Applicant also discloses that P1.7,16 is the serosubtype of strain H44/76, which has 30% PorA (see page 6, line 18 and page 25, table 1).

Berthet *et al.* differs from the instant application in that they do not disclose the use of serosubtype P1.16 in the vaccine composition.

Lehmann *et al.* disclose an outer membrane vesicle (bleb) vaccine comprising blebs from a meningococcal strain with the serosubtype P1.16 (see abstract).

"It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the

very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980). Therefore, it would have been obvious to one of ordinary skill in the art to use blebs from a meningococcal strain with the serosubtype P1.16 in the vaccine composition of Berthet *et al.*

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian J. Gangle whose telephone number is (571) 272-1181. The examiner can normally be reached on M-F 7-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on (571) 272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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ROBERT A. ZEMAN
PRIMARY EXAMINER